Post Market Clinical Follow-up Study for the Amvia/Solvia Pacemaker Family

Published: 14-11-2023
Last updated: 02-12-2024

The aim of this study is to collect data to confirm clinical safety and performance of the Amvia pacemaker family to fulfil the regulatory requirements for products that are available on the market. The collected data may also be used to support...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON56135

Source
ToetsingOnline

Brief title
BIO|MASTER.Amvia study

Condition

- Cardiac arrhythmias

Synonym
Bradyardia, slow heart rate

Research involving
Human

Sponsors and support

Primary sponsor: BIOTRONIK SE and Co.KG
Source(s) of monetary or material Support: BIOTRONIK SE & Co.KG

Intervention

Keyword: Bradycardia, heartfailure, pacemaker

Outcome measures

Primary outcome

The primary study objective is to collect clinical data on the performance and safety of the Amvia pacemaker by analyzing the SADE-d (i.e. SADE related to the device) free rate of the Amvia pacemakers at 6 months after implantation.

Secondary outcome

The main secondary objective is to confirm the clinical safety by analyzing the Amvia pacemaker related SADE-d events occurring during a period of 12 months after the implantation. Other secondary endpoints are the assessment of the available device algorithms and device measurements. For a complete overview on the endpoints see CIP section 8.1.3: endpoints.

Study description

Background summary

The Amvia pacemaker family, has been CE approved in the European Union since May 2023. This means that the Amvia pacemaker fulfils the European regulatory requirements for medical device products and therefore can be used in patients with a pacemaker indication (also outside clinical investigations). According to the Medical Device Regulation (EU) 2017/745 (MDR, Article 61 §4 and ANNEX XIV part B) a Post-Market Clinical FUP (PMCF) study is required as part of the post-market clinical follow-up and surveillance activities to confirm the safety and performance of the CE marked device throughout its expected lifetime. Thus, this study intends to collect data which will be used for regulatory purposes (MDR) in a post-market setting.

Study objective

The aim of this study is to collect data to confirm clinical safety and

performance of the Amvia pacemaker family to fulfil the regulatory requirements for products that are available on the market. The collected data may also be used to support further product development.

Study design

An open-label, prospective, international, multicenter, non-randomized study.

Intervention

Collection of safety and performance data during the implantation and follow-up of an Amvia pacemaker. A strict follow-up schedule needs to be followed in order to collect the necessary endpoint data from a device interrogation at the 2-, 6- and12-month follow-up after the implantation + usage of the BIOTRONIK Home Monitoring system.

Study burden and risks

This study is classified as a PMCF without invasive and/or burdensome procedures. As the implantation of the Amvia pacemaker thus not differ from the standard implantation procedure of a pacemaker, no study specific risks are associated with the implantation procedure. There are however possible risks that we do not know about at the moment (residual risks), even in a post market setting (after successful conformity assessment).
The timing of the study follow-up visits (2-, 6- & 12-month follow-up) might differ from the standard routine in the participating hospitals. The duration of the follow-up visits is increased compared to the routine follow-ups due to the data collection for the study on the device measurements and features. The usage of Home Monitoring is mandatory but this is not a burden for the subject rather an advantage as it allows for the early detection of events as this is in line with the current International Guidelines (already since 2015 the usage of Home Monitoring is endorsed by the HRS guidelines: with a Class I (A) recommendation that all patients with an Cardiac Implantable Electronic Device should be offered Remote Monitoring as part of the standard FUP management).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Standard Indication for de novo, upgrade or replacement pacemaker or cardiac resynchronization therapy pacemaker (CRT-P) implantation.
Ability and willingness to use the CardioMessenger and acceptance of the BIOTRONIK Home Monitoring® concept.

Exclusion criteria

Planned for the usage of "conduction system pacing"
Planned cardiac surgical procedures or interventional measures other than the study procedure within the next 12 months.
Age less than 18 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2024
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Amvia pacemaker family
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-11-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06018818
CCMO	NL84654.100.23